

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed December 9, 2009. Claims 1, 4-8, 13, and 21-33 were pending and rejected in view of cited art. Claim 32 is canceled and claims 1, 13, 21, 23-24, and 27-30 are amended.¹ Claims 1, 4-8, 13, and 21-31, and 33 remain pending in view of the above amendments, with claims 1, 21, and 24 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTIONS UNDER 37 C.F.R. 1.75(d)(1) AND 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office Action indicated that the specification lacks antecedent basis for the terms "to provide substantial longitudinal separation between the proximal and distal portions" as recited in claim 1 and "disposed end to end without overlapping" as recited in claim 21. The Office Action also rejected claims 1 and 21 under 35 U.S.C. § 112, first paragraph. In view of the amendment contained herein to remove the identified phrases, Applicant respectfully requests withdrawal of the objection and rejection.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1, 4-8, 21, 22, 24, 25, and 33 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,960,410 (*Pinchuk*) in view of U.S. Publication No.

¹ Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

2002/0072730 (*McGill*). Claims 13, 23, 26, 27, 30, and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Pinchuk* and *McGill* as applied to claims 4, 21, and 24, and further in view U.S. Patent No. 5,951,494 (*Wang*). Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Pinchuk*, *McGill*, and *Wang* as applied to claims 27, and further in view of U.S. Publication No. 2003/0050600 (*Ressemann*). Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Pinchuk* and *McGill* as applied to claim 1, and further in view of U.S. Patent No. 6,596,217 (*Davis-Lemessy*). Applicant traverses the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims.

As noted by Applicant's specification, the invention recited in independent claims 1, 21, and 24 is directed to a balloon catheter with higher pushability. This increased pushability characteristics can be achieved through inclusion of a reinforcing pipe with a friction reducing coating, thus making balloon catheter handling easier.

As presented herein for reconsideration (see independent claim 1, as exemplary), the balloon catheter claimed in independent claim 1 includes a catheter shaft having proximal and distal ends, with "an inflation balloon disposed on the distal end." A guiding wire lumen is disposed within the catheter shaft, "the guiding wire lumen being formed from a pipe having coupled proximal and distal portions." "[T]he proximal and distal portions of the pipe being made of a solid material, the material of the proximal portion being more rigid than the material of the distal portion and the proximal portion of the pipe including a friction reducing plastic tube disposed within a lumen of the proximal portion."²

As presented herein for reconsideration, the independent claims are not anticipated nor made obvious by *Pinchuk* either singly or in combination with any other cited reference.³ In

² The other independent claims 21 and 24 recite, in part, and respectively, "a friction reducing plastic tube being disposed within a lumen of the pipe and forming the first borehole" and "the first borehole defines a guiding wire lumen and the second borehole defines an inflation lumen for connecting the connecting piece to the inflatable balloon, a portion of the first borehole being formed from a lumen of the friction reducing plastic tube."

³ *McGill*, *Wang*, *Ressemann*, and *Davis-Lemessy* were cited as a secondary references. *McGill* was cited for the proposition that it discloses "a kink protection portion" and that "proximal and distal pipes meet end to end without overlapping at a transition, wherein a kink protection is provided about the transition at least partially overlapping the proximal and distal pipes" (Office Action, p. 5). *Wang* was cited for the proposition that it discloses "coating the interior of a catheter lumen with a tube of TEFLON (Col. 16, lines 60-64), which can extend for any length of the tube" (Office Action, p. 6). *Ressemann* was cited for the proposition that it discloses "plasma treating for increasing adherence", while *Davis-Lemessy* was cited for the proposition that it discloses "use of a nylon tube in the construction of a catheter" (Office Action, pgs. 6 and 7). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Pinchuk*. Thus, even assuming *arguendo* that any of the references to *McGill*,

particular, *Pinchuk* discloses a catheter 10 having an inner tube 22 that can receive a guidewire (see col. 2, ll. 64-67). The inner tube 22 includes a plastic tube 60 that extends from a bifurcated adapter 30 at the proximal end" completely through the catheter 10 to the catheter's distal tip 24" (Col. 2, ll. 51-52). No mention is made of this inner tube 22 including another tube within, rather, "[a] second more flexible tube or sheath 64 covers and is bonded to the reduced diameter portion of the tube 60 " which begins "slightly proximal of the balloon 12" disposed at the distal end of the inner tube 22 (Col. 3, ll. 45-46 and 20-21). Applicant respectfully submits that *Pinchuk* fails to disclose that "the proximal portion of the pipe include[ed] a friction reducing plastic tube disposed within a lumen of the proximal portion," "a friction reducing plastic tune [is] disposed within a lumen of the pipe and forming the first borehole," and "the proximal pipe including a friction reducing plastic tube disposed within the first proximal pipe," as recited and claimed in independent claims 1, 21, and 24, respectively.

Accordingly, for at least the reasons noted, independent claims 1, 21, and 24 and the claims depending therefrom are neither anticipated nor made obvious by *Pinchuk*, either singly or in combination with any other prior art of record, and thus reconsideration and withdrawal of the rejections under Section 103 is respectfully requested.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner

Wang, *Ressemann*, and *Davis-Lemessy* are properly combinable with *Pinchuk*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Pinchuk*.

In addition to the above, Applicant respectfully disagrees with the characterization of *Wang*. As noted above, *Wang* was cited for the proposition that it discloses "coating the interior of a catheter lumen with a tube of TEFLON (Col. 16, lines 60-64)." The identified portion of *Wang* appears to describe the use of a "teflon-coated metal rod as a mandrel" used during the manufacture of "helically orientated materials with inner lumens" (*Wang*, col. 16, ll. 51-54). "Since the teflon coating on the exterior of the mandrel has a higher affinity for the orientated polymer than the metal rod" upon removing the mandrel from the lumen of the polymer tube "a thin coating of teflon" remains on the "lumen walls" of the polymer tube (col. 16, ll. 57-62). From Applicant's review, it appears that *Wang* discloses the

Application No. 10/511,911
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provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 8th day of March, 2010.

Respectfully submitted,

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inclusion of a teflon coating on the lumen walls of a polymer tube and not, as the Office Action suggests, a "tube of TEFLON."